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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/608,799 | 06/27/2003 | Paul Stanish | 37031-23 | 6833 |
| 7590 | 01/19/2006 | | EXAMINER | |
| Woodard, Emhardt, Moriarty, McNett & Henry LLP Bank One Center/Tower Suite 3700 111 Monument Circle Indianapolis, IN 46204-5137 | | | PREBILIC, PAUL B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |
| DATE MAILED: 01/19/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/608,799 | STANISH, PAUL |
| | Examiner Paul B. Prebilic | Art Unit 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 November 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 10-15, 26, 30-44, 51, 56, 57 and 61 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 16-25, 27-29, 45-50, 52-55 and 58-60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 June 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/27/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

Election/Restrictions

Applicant's election with traverse of Group I, Species A (Figure 3), and Species Y (Figures 9 and 10) in the reply filed on November 1, 2005 is acknowledged. The traversal is on the ground(s) that there was no restriction made in the parent application and it was examined by Examiner Prebilic. This is not found persuasive because the parent application was examined by Examiner Gilpin with Examiner Prebilic merely the primary examiner that reviewed and signed the office actions. Furthermore, the restriction requirement set forth in this application points out the burden of examining the multiple inventions, and the Applicants have not sufficiently traversed the Examiner's position.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-15, 26, 30-44, 51, 56, 57, and 61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 1, 2005. Even though the Applicants did not include these claims as the ones drawn to a non-elected invention or species, claims 10 and 56 have been withdrawn because there are directed to non-elected Species B (Figure 4) and not elected Species A (Figure 3). Similarly, claims 26, 51, and 61 have been withdrawn because they were directed to Species X (Figure 8) and not to elected Species Y (Figures 9 and 10).

Claim Objections

Claim 56 is objected to because of the following informalities: Although this is a withdrawn claim, the Examiner wanted to point out that there is no period at the end of this claim so that it will noted should the claim be rejoined in the future. Appropriate correction is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-10, 18-20, 22-24, 26-29, 45, 46, and 51-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 7, 9, 10, 12, 22-24, and 26-29 of U.S. Patent No. 6,585,762. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the present claims are read on by patented claims such that they are clearly obvious in view thereof.

Claims 1, 3-5, 7-10, 16, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-10, 22, and 23 of copending Application No. 10/344,221. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are read on by the copending claims such that they are considered to be clearly obvious in view thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 8, 9, 16, 18-20, 22, 24, 25, 27, 45, 47-50, 52, 54, 55, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki (US 3,683,926). Suzuki anticipates the claim language fully; see Figures 1A and 1B, column 3, lines 22-26 and lines 50-54, and column 4, lines 9-26. The groove as claimed is between the

protuberances of Suzuki, and the tube of Suzuki can be 20 mm or 2 cm long. Therefore the grooves or protuberances are “at least about 1 centimeter” or 10 mm from the orifices as claimed.

Claims 1-9, 18, 19, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Dossa (US 6,338,724). Dossa anticipates the claim language where the first end as claimed is the end of the catheter (18) or end of the thinner end of graft (12). The second end if the larger end of graft (12); see Figure 1 and column 3, lines 16-61.

With regard to claims 3-5, the graft has a 6 mm diameter end and a 6 to 14 French end where 6 French is approximately 1.6 to 2.0 mm in diameter and 14 French is approximately 4.2 to 4.8 mm in diameter.

With regard to claim 18, the first tubular section is the larger diameter portion of graft (12) of Dossa.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 20, 22, 24, 25, 27-29, 45, 47-50, and 52-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dossa (US 6,338,724) in view of Coulson et al (article entitled “Modification or Venous End . . .”) or Hughes et al (US 4,728,328). Dossa meets the claim language as explained in the Section 102 rejection supra but fails to disclose the use of a cuff therewith as claimed. However, both Coulson and

Hughes teach that it was known to put cuffs on the ends of similar grafts to improve the connection of the same to the blood vessel. Therefore it is the Examiner's position that it would have been obvious to put cuffs on the ends of the Dossa device for the same reasons that Coulson or Hughes does the same, in order to improve the connection of the graft to the blood vessel.

Claims 17, 23, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dossa, Coulson, and Hughes as applied to claims 16, 20, 22, 24, 25, 27-29, 45, 47-50, and 52-60 above, and further in view of Kalis (US 5,609,624). With regard to claims 17, 23, and 46, Dossa as modified by Coulson or Hughes do not suggest a 45-degree angle groove as claimed. However, Kalis teaches that it was known to put ribs (with grooves between the adjacent ribs at angles from 15⁰ to 165⁰) along the outside of a graft to support or reinforce the graft along that section; see Figures 6-8, column 5, line 29 to column 6, line 25 and claims 9 and 18. Therefore, it is the Examiner's position that it would have been obvious to angle to protuberances or grooves of Dossa as modified by Coulson or Hughes for the same reasons that Kalis does the same.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738